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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,416	12/31/2003	Paul Cooper	1671-0289	4647

7590 12/23/2005

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EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 12/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/750,416	Applicant(s) COOPER ET AL.	
	Examiner Mary Hoffman	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
 4a) Of the above claim(s) 15 and 34-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 16-33, and 41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/24/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, Species "A", claims 1-14, 16-33, and 41 in the reply filed on 12/05/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 15 and 34-40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12/05/2005.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: ref. #s 26a, 32a, 238b, 238a, 98, 90, and 108. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top

margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 19 is objected to because of the following informalities:

In claim 19, "the cross bar and the frame component providing controlled compression of a bone or joint retained by fixation wires tied to the frame component and the cross bar" should be changed to --the cross bar and the frame component being capable of providing controlled compression of a bone or joint retained by fixation wires tied to the frame component and the cross bar-- because it is unclear whether or not applicant is claiming a part of the human body.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Szabo (U.S Patent 5,885,282).

Szabo discloses an external bone/joint fixation component comprising a one-piece frame (see FIG. 1) having a posterior portion (ref. # 14) lying essentially in a first plane and an anterior portion transverse to the posterior portion lying essentially in a

second plane (ref. #52). There is a first plurality of fixation bores disposed in the posterior portion and a second plurality of fixation bores disposed in the anterior portion, each capable of receiving a wire fixator adapted to receive an end of a fixation wire. The second plane lies at an angle of between 70 and 110 degrees from a perpendicular to the first plane, specifically at an angle of 90 degrees. The frame is fabricated from a material exhibiting a small flexibility. The posterior portion comprises an arcuate section. The arcuate section incorporates a frame stress reduction radius. The anterior portion extends above the first plane.

Claims 19, 21-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Moorcroft et al. (U.S Patent 6,328,737).

Moorcroft et al. an external bone/joint fixation device comprising a frame component (see FIG. 1) defined by a posterior portion (ref. #221) and an anterior portion (bars, ref. #225) disposed transverse to the posterior portion, the frame component including a plurality of first fixation bores (ref. #228) each of which is capable of receiving a wire fixator that is adapted to receive an end of a fixation wire; and a cross bar component (see piece connecting bone pin ref. #14 to bone) attachable to the anterior portion of the frame component and having a plurality of second fixation bores (see bore and elongate slot in piece connecting bone pin ref. #14 to bone) each of which is capable of receiving a wire fixator that is adapted to receive another end of the fixation wire, the cross bar and the frame component being capable of providing controlled compression of a bone or joint retained by fixation wires tied to the frame component and the cross bar. The external bone/joint fixation device further comprising

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first and second cross bar holders capable of attaching to the anterior portion of the frame component and for receipt of an end of the cross bar (ref. #201). Each cross bar holder is configured to clamp against an end of the cross bar when the cross bar holder is mounted to the anterior portion of the frame component (col. 2, lines 53-55). The anterior portion extends above a first plane defined by the posterior portion. The external bone/joint fixation device further comprises a posterior angulation component capable of being received on the posterior portion (ref. #227). The posterior angulation component is adjustably positionable on the posterior portion. The posterior angulation component is adjustably positionable on the posterior portion through attachment thereof in one or more of the first fixation bores. The external bone/joint fixation device further comprises an elevator capable of extending about a bottom portion of the frame component and allowing access to a sole of the foot (ref. #240). The elevator is capable of evenly distributing pressure applied thereto. The elevator is arcuate shaped.

Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Volkov et al. (U.S. Patent No. 4,338,927).

Volkov et al. disclose an external bone/joint fixation component comprising a modular frame (col. 2, lines 40-42) having a posterior portion lying essentially in a first plane (FIG. 1, ref. #1) and an anterior portion transverse to the posterior portion and lying essentially in a second plane (FIG. 1, ref. #4), and a first plurality of fixation bores disposed in the posterior portion and a second plurality of fixation bores disposed in the anterior portion (FIG. 1, ref. #12) each of which is capable of receiving a wire fixator that is adapted to receive an end of a fixation wire.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4, 7, 8, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szabo (U.S Patent 5,885,282).

Szabo discloses the claimed invention except for the material of the frame exhibiting a small flexibility of less than 0.5 mm in the second plane and less than 2.0 mm in the first plane, the frame stress reduction radius is between 0.06 inches and 1.5 inches, the frame thickness being between 0.06 and 0.5 inches, and the frame being fabricated from material a composite material, a polymer, a metal alloy, a shape memory material, or a radiolucent material. With regard to claims 4, 7 and 8, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the frame of Szabo of a material exhibiting a flexibility in the range of less than 0.5 mm in the second plane and less than 2.0 mm in the first plane, the frame stress reduction radius in the range of 0.06 inches and 1.5 inches, the frame thickness being in the range between 0.06 and 0.5 inches, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Furthermore, it would have been obvious to one having ordinary skill in the art at the

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time the invention was made to construct the frame of Szabo of a material such as a composite material, a polymer, a metal alloy, a shape memory material, or a radiolucent material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Szabo (U.S. Patent 5,885,282) in view of Blyakher (U.S. Patent No. 5,776,132).

Szabo discloses the claimed invention except for calibration markings disposed on the posterior portion.

Blyakher discloses calibration markings disposed on a posterior portion of an external fixation assembly for identify the placement of connecting rods and retaining means for half pins and wires (col. 3, lines 53-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the external fixation assembly of Szabo with calibration markings disposed on a posterior portion in view of Blyakher in order to identify the placement of connecting rods and retaining means for half pins and wires.

Claims 1, 9-14, and 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szabo (U.S. Patent 5,885,282).

Szabo discloses an external bone/joint fixation component comprising a multi-piece frame having a posterior portion (ref. #14) lying essentially in a first plane and an anterior portion transverse to the posterior portion and lying essentially in a second plane (ref. #12). There is a first plurality of fixation bores disposed in the posterior

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portion and a second plurality of fixation bores disposed in the anterior portion, each capable of receiving a wire fixator adapted to receive an end of a fixation wire. The external bone/joint fixation component further comprises a cross bar (see bar attached to circle ref. #12, similar to bar of ref. #56) capable of being attached to the anterior portion of the frame in a plurality of angular positions relative to the first plane. The cross bar has a plurality of cross bar bores (ref. #60) each of which are capable of receiving a wire fixator that is adapted to receive another end of the fixation wire. The cross bar is also rotatable about a longitudinal axis of the cross bar (col. 4, lines 35-39) . The external bone/joint fixation device further comprises first and second cross bar holders capable (ref. #66) of attaching to the anterior portion of the frame and for receipt of an end of the cross bar. Each cross bar holder is capable of clamping against an end of the cross bar when the cross bar holder is mounted to the anterior portion of the frame. The anterior portion extends above the first plane. The posterior portion is capable of capturing the posterior aspect of a foot. The anterior portion has first and second legs (ref. #18a and 18c) respectively extending from the posterior portion, and a transverse section (ref. # 84) extending from the first and second legs. The bores in the cross bar are capable of receiving a wire fixator that is adapted to receive another end of the fixation wire, the cross bar and the frame component being capable of providing controlled compression of a bone or joint retained by fixation wires tied to the frame component and the cross bar.

The external bone/joint fixation further comprises a posterior angulation component (ref. # 56) capable of being received on the posterior portion and includes a

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wire retention bore adapted to receive a fixator for receipt of another end of the fixation wire. The posterior angulation component is adjustably positionable on the posterior portion through attachment thereof in one or more of said first fixation bores.

Szabo discloses the claimed invention except for device being formed as one piece. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Moorcroft et al. as one piece, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Claims 30 and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moorcroft et al. (U.S Patent 6,328,737).

Moorcroft discloses the claimed invention except for the frame component is formed as one piece, calibration markings disposed on the posterior portion, and the frame is being fabricated from a composite material, a polymer, a metal alloy, a shape memory material, or a radiolucent material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Moorcroft et al. as one piece, since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893). Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the frame of Szabo of a material such as a composite material, a polymer, a metal alloy, a shape memory material, or a radiolucent material, since it has

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been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 125 USPQ 416.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moorcroft et al. (U.S. Patent 6,328,737) in view of Blyakher (U.S. Patent No. 5,776,132).

Moorcroft et al. disclose the claimed invention except for calibration markings disposed on the posterior portion.

Blyakher calibration markings disposed on a posterior portion of an external fixation assembly for identify the placement of connecting rods and retaining means for half pins and wires (col. 3, lines 53-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the external fixation assembly of Moorcroft et al. (U.S. Patent 6,328,737) with calibration markings disposed on a posterior portion in view of Blyakher in order to identify the placement of connecting rods and retaining means for half pins and wires.

Conclusion

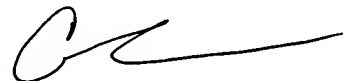
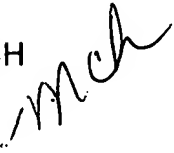
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See attached PTO-892

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCH



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